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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB

HANMI'S RESPONSIVE *MARKMAN* SUBMISSION

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Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively "Hanmi") respectfully submit this Responsive brief in support of Hanmi's proposed claim constructions.

I. Hanmi's Proposed Constructions For The '504 Patent Should Be Adopted

A. "alkaline salt"

None of the individual aspects of AstraZeneca's proposed construction is found in the '504 specification: (-)-omeprazole being "negatively charged," or the term "basic salt," or the term "suitable for use in a pharmaceutical formulation." AstraZeneca further defines "basic salt" as a salt of (-)-omeprazole "that is generated under basic or alkaline conditions, or one that generates a basic or alkaline solution when put into water." (D.I. 133, AstraZeneca Opening Markman Submission "AZ Br." 8) Neither of these concepts is found in the '504 patent's intrinsic record.

Instead, AstraZeneca's immediate focus is on extrinsic evidence – Declaration testimony of Dr. Davies, and a chemical dictionary. (AZ Br. 8.) AstraZeneca's proposed construction of "alkaline salt" not only relies on extrinsic evidence and finds no support in the intrinsic record but also is also completely inconsistent with the understanding of one skilled in the art. Dr. Davies opines that the term "alkaline" *derives* from the alkali and alkaline earth metals, Groups I and II of the periodic table, and concludes that suitable cations for forming an alkaline salt would include at least these metals. (D.I. 133-3, Davies Decl. ¶ 36.) Again, however, the '504 patent's intrinsic record does not mention "alkali metal salts," "alkaline earth metal salts," or "Groups I and II of the periodic table."

Incredibly, while relying mainly on extrinsic evidence, AstraZeneca completely ignores the first sentence a reader encounters on the cover page of the '504 patent: "[t]he novel optically pure compounds Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of [the enantiomers of omeprazole]." D.I. 86-2, Abstract.

Even more amazingly, AstraZenenca *completely ignores* the '504 patent's *express definition of* salt scope:

> ***The present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of the single enantiomers of omeprazole***, where R is an alkyl with 1-4 carbon atoms, i.e. Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole and (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, where R is an alkyl with 1-4 carbon atoms."

(D.I. 86-2, col. 2, ll. 42-49 (emphasis added).) As urged in Hanmi's Opening *Markman* Submission (D.I. 132) ("Hanmi Br.") at pages 2-3, this definition of the scope of "the present invention" and the plain-English Abstract limit the scope of the '504 patent claims to the six salt species recited. *See Honeywell Int'l, Inc. v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (even though the claim used broader language, it was limited to a fuel filter because the specification referred to the fuel filter as "this invention" and "the present invention"); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.,* 595 F.3d 1340, 1353 (Fed. Cir. 2010) (reference to "the present invention" was found to limit the claimed re-centering command to require a manual input, specifically, a mouse click); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("The 'Disclosure of the Invention' section of the '880 patent begins with a description of the gateway system of the 'present invention.' '880 patent col. 4 ll. 1-6. In the course of describing the 'present invention,' the specification then states that "[t]he gateway compresses and decompresses voice frequency communication signals and sends and receives the compressed signals in packet form via the network." *Id.* ll. 12-15. When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention. The Federal Circuit has made clear that the precise language used in the '504 patent -- "*the present invention refers to*" -- limits the scope of the claims to the six disclosed species.

Moreover, the phrase "refers to" clearly is a definitional transition phrase. For example, in *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328 (Fed. Cir. 2000), the patent specification contained a definition using "refers to" as set forth below:

> "As used herein, the expression 'water-soluble polydextrose' (also known as polyglucose or poly-D-glucose) specifically refers to the water-soluble polydextrose prepared by melting and heating dextrose (also known as glucose or D-glucose), preferably with about 5-15% by weight of sorbitol present, in the presence of a catalytic amount (about 0.5 to 3.0 mol %) of citric acid."

224 F.3d at 1330. Although the claims only recited "polydextrose," the district court held and the Federal Circuit affirmed that "the definition of 'water-soluble polydextrose' in the specification limited the claims to polydextrose produced with citric acid as a catalyst." *Id.* at 1331.

Nonetheless, AstraZeneca's expert, Dr. Davies, admitted that he did not specifically consider this language of the '504 patent in formulating his definition of "alkaline salts." (Exhibit ("Ex.")[1] 1, Davies Tr. 165-166). Given AstraZeneca's election to simply ignore the most critical aspects of the intrinsic record, no credibility should be given to its contrived, extrinsic evidence-based position.

AstraZenenca places its bet on the phrase "exemplified by" based on the what is at best ambiguous language in column 5, lines 7-11. (AZ Br. 9). Read in context, this sentence would not be understood as a broadening of the specific definition preceding it, but rather as confirmation that the proper scope of the claimed subject matter includes both the Mg^{2+} and Na^{+} salts of (-)-omeprazole (which were made), and the four species which were not made, Li^{+}, K^{+}, Ca^{2+}, and $N^{+}(R)_4$, where R is an alkyl with 1-4 carbon atoms.

Based on Dr. Davies' Declaration (D.I. 133-3 at ¶¶ 36-37), AstraZeneca argues that "alkaline salt" includes "at least, the alkaline metals and alkaline earth metals of Groups I and II

[1] Exhibits referenced herein are attached to the concurrently filed Declaration of Renita S. Rathinam.

of the periodic table" (AZ Br. 8). Dr. Davies explains that this group includes beryllium, rubidium, caesium, barium and radium (Davies Decl. ¶ 36), each of which is toxic to humans and even *radioactive* in the case of radium! *See* Supplemental Declaration of Jerry Atwood, Ph.D. ("Supp. Atwood Decl.") ¶¶ 11-23. Moreover, while asserting that all alkaline metals of Group I are included, AstraZeneca forgot to list francium (Fr) -- a highly radioactive metal. *Id.* ¶ 18. Clearly, one of ordinary skill in the art would not use toxic or radioactive cations to prepare the desired salt forms. (Supp. Atwood Decl. ¶¶ 18-23.) AstraZeneca's insistence that all these materials are encompassed by the '504 patent claims completely undermines its far-reaching proposed construction, and provides all the more reason why the definition of the six salts disclosed in the specification should be adopted.

Dr. Davies went further and included all metals of the periodic table within his definition of "alkaline salt" (Ex. 1, Davies Tr. 160), most of which are toxic. (Supp. Atwood Decl. ¶ 23.) Persons of ordinary skill in the art would understand that most metals referred to by Dr. Davies are toxic at a level required to achieve a pharmaceutical effect of (-)-omeprazole. (*Id.*) For example, administration of a lead salt to humans would have disastrous consequences. *(Id.)*

One skilled in the art reading the '504 patent and its file history would not, in the absence of any relevant disclosure, conclude that the patentees intended or conceived as part of their invention salts formed from these toxic and radioactive metals. As such, AstraZeneca's reliance on highly toxic and radioactive metals demonstrates that its construction cannot be correct.

Dr. Davies includes the ammonium (N^+H_4) and tetraalkyl ammonium (N^+R_4) salts as alkaline salts of the claim, but neither species has any relationship to Groups I and II and N^+H_4 is not even listed in the patent. Astonishingly, Dr. Davies is uncertain that an ammonium salt of (-)-omeprazole could even be made, and he doubts a tetrabutyl ammonium salt could be formed as a solid. (Supp. Atwood Decl. ¶ 30; Ex. 1, Davies Tr. 151-154.)

Dr. Davies includes within his definition salts such as pentamethyl guanidine salts and guanidium salts, but excludes other amines such as pyridine or piperidine salts, as well as amino acids. (Supp. Atwood Decl. ¶ 29; Ex. 1, Davies Tr. 158-59, 170-71). In his view, organic salts that form strong bases would be included in his definition and those which do not are excluded. (*Id.*) Of course, nothing in the patent supports such an arbitrary selection of "alkaline salts." There is nothing in the patent, file history, AstraZeneca's Opening Brief or Dr. Davies' Declaration that supports a scope of "alkaline salts" defined by the strength of the base that would be formed. There are no benchmarks for base strength, no definition of strong and weak bases, and no guidance as to how to determine in advance whether an unnamed salt would meet Dr. Davies capricious criteria for alkaline salts. (Supp. Atwood Decl. ¶ 29.)

The '504 patent provides two different procedures for preparing the disclosed salt species, one for magnesium and one for sodium, but no guidance is provided as to which procedure should be used for undisclosed species, or why. (Supp. Atwood Decl. ¶¶ 24, 25.) Persons of ordinary skill would not know which procedure should be used to prepare further alkaline salts of (-)-omeprazole. Dr. Davies has previously confirmed that persons skilled in the art "would have no expectation that a salt of an enantiomer could be formed." (Supp. Atwood Decl. ¶31; Ex. 1, Davies Tr. 176-78; Ex. 6).

Given the large number of toxic salts within Dr. Davies' definition, his doubt about whether some of them could be prepared by arbitrary reliance on base strength as a determinant for selecting organic salts, and the lack of guidance in the '504 patent about the preparation of undisclosed species, persons skilled in the art would not know whether a particular "alkaline salt," according to Dr. Davies, was within the scope of the patent or not. Accordingly, AstraZeneca's construction cannot be correct.

As expected, AstraZeneca relies on claim differentiation in support of its proposed construction (AZ Br. 9-10), but the presumption is overcome here (*see* D.I. 132, Hanmi's

Opening *Markman* Submission ("Hanmi Br.") at 7). Indeed, as the Federal Circuit has made clear, claim differentiation is a guide, not a rigid rule:

> Different claims with different words can, of course, define different subject matter within the ambit of the invention. On the other hand, claim drafters can also use different terms to define the exact same subject matter. Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter. *Tandon Corp. v. U.S. Int'l Trade Comm'n,* 831 F.2d 1017, 1023 (Fed. Cir. 1987); *Hormone Research Found. v. Genentech, Inc*., 904 F.2d 1558, 1567 n.15 (Fed. Cir. 1990) ("It is not unusual that separate claims may define the invention using different terminology, especially where (as here) independent claims are involved."). In this context, this court has cautioned that "claim differentiation is a guide, not a rigid rule." *Laitram Corp. v. Rexnord, Inc*., 939 F.2d 1533, 1538 (Fed. Cir. 1991).
>
> With those precedents in mind, this court observes that two considerations generally govern this claim construction tool when applied to two independent claims: (1) claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous; and (2) claim differentiation "can not broaden claims beyond their correct scope." *Fantasy Sports Props. v. Sportsline.com,* 287 F.3d 1108, 1115-16 (Fed. Cir. 2002) (quoting *Kraft Foods, Inc. v. International Trading Co.*, 203 F.3d 1362 (Fed. Cir. 2000)). In this case, both of those considerations weigh against the district court's construction of "adjustable."

Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380-81 (Fed. Cir. 2006). The '504 patent's clear ***definition*** at col. 2, lines 42-49 -- entirely ignored by AstraZeneca -- "The present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts," trumps claim differentiation. The claims should not be found to encompass all alkaline salts or "basic" salts as AstraZeneca now urges.

AstraZeneca likewise ignores the '504 prosecution history as a whole, which confirms a claim scope that is no broader than the six species that are described in the originally filed '512 application and the issued '504 specification (Hanmi Br. 2-6). As filed, every claim of the '512 application was limited to the six salt species disclosed in the specification. (*Id.* at 4-5.) During prosecution, AstraZeneca broadened the scope of the claims to try to include all alkaline salts. Citing no support within the specification for its broadening amendment, and based on a Declaration describing the testing of only two salts species of (-)-omeprazole, AstraZeneca

erroneously argued to the Patent Office that the data on the two salt species "***support[ed] the full scope of the genus of alkaline salts disclosed in the application and as claimed herein.***" The full scope of the genus disclosed in the application was limited to the six species actually recited. There was not then, and is not now, any evidence of record showing that the scope of alkaline salts is any broader than the actual disclosure of the six recited species. (*Id.* at 5-6)

A genus encompassing every existing alkaline salt, including the toxic and radioactive ones suggested by Dr. Davies, is without a doubt nowhere disclosed or suggested in the '504 patent or prosecution history. AstraZeneca's suggestion that data on these two commonly used alkaline salts is sufficient to support a genus of every known alkaline salt, whether or not disclosed, is untenable.

AstraZeneca and Dr. Davies urge that the "alkaline salt" term in the claims of the '504 patent also include a pharmaceutical acceptability limitation, *i.e.*, they must be "suitable for use in pharmaceutical formulation." (AZ Br. 8; Davies Decl. ¶ 41.) Yet nowhere in the '504 patent specification or prosecution history is it defined or required that the alkaline salt independently be suitable for use in a pharmaceutical formulation. The patent specification refers to pharmaceutically acceptable carriers, pharmaceutically acceptable enteric coating materials, and pharmaceutically acceptable solvents. These descriptions show that the '504 patentees knew how to describe individual components of a formulation as pharmaceutically acceptable. That they chose to require other components of the formulation to be "suitable for use in a pharmaceutical formulation," -- *but not alkaline salts* -- demonstrates that the term "alkaline salt" is not so limited. (Supp. Atwood Decl. ¶¶ 33-36.) Nor does it follow that that a formulation of claim 1 necessarily requires that the alkaline salt also be independently suitable for use in a pharmaceutical formulation, because a person of ordinary skill in the art would understand that an alkaline salt -- otherwise *unsuitable* for use in a pharmaceutical formulation for any one of a

variety of reasons -- can be made to be suitable by formulation, modification and other techniques. (*Id.* ¶¶ 37-41.)

Moreover, during his deposition, Dr. Davies went even further and grafted a "testing" requirement onto his "suitability" definition (Ex. 1, Davies Tr. 173-174). Based only on the language of the claims, Dr. Davies construes that the "alkaline salts" are those "suitable for use in a pharmaceutical formulation." (Davies Decl. ¶ 41.) However, during his deposition, he plainly conceded that one of ordinary skill in the art would need to perform experimentation to determine if his vast field of potential salts would – in fact – be pharmaceutically acceptable. (Davies Tr. 173-174). This entire concept of having to test potential salts is far afield from any aspect of the intrinsic record. There is nothing about the type of testing, the methodology, the standards used to determine alleged suitability, etc. in the '504 patent. AstraZeneca and Dr. Davies create and rely on new concepts requiring nebulous testing in order to support their present construction of alkaline salts. This practice simply does not comport with the manner in which a person of ordinary skill in the art determines the meaning of a claim term. (Supp. Atwood Decl. ¶ 33.)

In the earlier *DRL* litigation before this Court, AstraZeneca argued (and Dr. Davies supported) that the definition of alkaline salt in the '504 patent claims was "a compound of positively- and negatively-charged ions (cations and anions) formed under basic conditions." (Case 3:05-cv-05553-JAP-TJB (D.I. 188, p. 10)). Nowhere in its previous proposal to this Court did AstraZeneca suggest that "alkaline salts" of the '504 patent claims contained a limitation that they are "suitable for use in a pharmaceutical formulation."[2] It is beyond any argument that

[2] Dr. Davies attempted to explain the difference in the two proposed constructions by stating that in the *DRL* litigation, he defined what an alkaline salt *is*, and in the present litigation, he defines alkaline salt *in the context of claim 1*. (Ex. 1, Davies Tr. 80-82). That explanation is senseless, and does not meaningfully describe why AstraZeneca has proposed two different definitions of the term "alkaline salt" to the Court. (*See* Supp Atwood Decl. ¶ 42.)

AstraZeneca's present construction -- *including its pharmaceutical acceptability limitation* -- is a litigation-inspired attempt to preserve the validity of its claims by narrowing Dr. Davies' boundless universe of alkaline salts. The claimed salts of the '504 patent either contain a pharmaceutical suitability limitation or they do not. AstraZeneca's present construction is inconsistent with its previous one, and should not be countenanced.

B. "(-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" and "optically pure"

AstraZeneca is wrong in stating that the Court rejected the very arguments advanced by Hanmi here (AZ Br. 11). To be clear, Hanmi was not a party to the prior case, and it is not apparent that any defendant properly explained that the '504 patent *expressly defines* two levels of optical purity — "optically pure" and "very high optical purity:"

> With the expression "***optically pure*** Na^+ salts of omeprazole" ***is meant*** the (+)-enantiomer of omeprazole Na-salt essentially free of the (-)-enantiomer of omeprazole Na-salt and the (-)-enantiomer essentially free of the (+)-enantiomer, respectively.
>
> * * *
>
> Because it is possible to purify optically impure or partially pure salts of the enantiomers of omeprazole by crystallization, they can be obtained in ***very high optical purity, namely*** ≥99.8% enantiomeric excess (e.e.) even from an optically contaminated preparation.

(Col. 3, ll. 31-36 and 43-48) (emphasis added)).

Dr. Davies correctly asserts in his "Appendix" (D.I. 133-4 ("Davies App.")), paragraph 2, that the term "(-)-enantiomer" limits the chemical name to mixtures enriched in (-)-omeprazole. But then he goes on to incorrectly tack on numerical values found only in the working Examples. (Davies App. ¶¶ 10-17.) In doing so, both AstraZeneca and Dr. Davies ignore the express definition of "optically pure" as "the (-)-enantiomer essentially free of the (+)-enantiomer." This is an incorrect approach because the law is clear that an express definition of a claim term in the specification controls in claim construction. *See, e.g., AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051 (Fed. Cir. 2010) ("In such cases, the inventor's lexicography governs.") (quoting

Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*)); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.").

Accordingly, the term "optically pure" in claim 2 should be accorded its express definition in column 3 – "the (-)-enantiomer essentially free of the (+)-enantiomer." (D.I. 86-2, col. 3, ll 31-36). AstraZeneca cannot change the definition years later. One of ordinary skill in the art would have understood that the term "optically pure" in claim 2 would be given its *express definition* in column 3, lines 31-36. (Supp. Atwood Decl. ¶ 58.) Yet, AstraZeneca and Dr. Davies rely essentially solely on the Examples of the '504 patent and a prior art reference to read lower numerical limits into the claims, which is improper for the reasons set forth Hanmi's Opening Br. pp. 2, 10-14 (D.I. 132). (Supp. Atwood Decl. ¶ 59.) *See also Superguide Corp. v. DirecTV Enterprises, Inc.,* 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

AstraZeneca fails to explain why the '504 patent "Examples" should be treated, not as illustrative, but as defining the scope of the alleged invention. That is the role of the claims. There is absolutely nothing in the '504 patent to indicate that the Examples should be treated as anything but ordinary examples. (Supp. Atwood Decl. ¶ 59.) On the contrary, the '504 specification prefaces the Examples with the following unambiguous statement: "The invention is ***illustrated*** by the following ***examples*** using ***preferred procedures*** for the preparation of optically pure sodium salts and magnesium salts." (D.I. 86-2 at col. 6, ll. 26-28 (emphasis added)). Nonetheless, Dr. Davies opines that the use of the term "illustrated" signaled a limiting

definition of the optical purity of the claimed compounds based strictly on the examples that followed this statement. (Ex. 1, Davies Tr. 209-210; Supp. Atwood Decl. ¶¶ 58-60.)

AstraZeneca's rationale for this improper importation of the Examples into the claims begins with the prior art 1990 Erlandsson publication (D.I. 133-5, Ex. 8), which is discussed in the Background section of the '504 patent (D.I. 86-2 at col. 1, ll. 27-29; D.I. 133-4 Davies App. ¶¶ 7-9); Supp. Atwood Decl. ¶ 61). According to Dr. Davies, the "patent provides (-)-omeprazole at an optical purity not provided by prior art methods." (Davies App. ¶ 6.) Because the Erlandsson reference disclosure of (-)-omeprazole in an optical purity of 95.6% (91.2% e.e.) is prior art, Dr. Davies concludes that the '504 patent claims cannot be construed to include compounds having optical purity at the levels disclosed in the Erlandsson reference, even though (1) the express definition of "optically pure" in the '504 patent is not defined by a numerical value; and (2) none of the claims contain a numerical value as a limitation on optical purity. Dr. Davies' methodology, as well as his reading of the Erlandsson reference, are flawed. (Supp. Atwood Decl. ¶ 61.)

First, there is no dispute that the Erlandsson reference is directed to the separation of racemic omeprazole into its enantiomers, which are obtained in neutral form, *i.e.*, as free bases and not as salts as recited in the asserted claims 1-7 and 10 of the '504 patent. Distinguishing the claimed salts of the enantiomers from the prior art disclosures of the neutral forms, the '504 patent states:

> There is no example in the known prior art of any isolated or characterized salt of optically pure omeprazole, *i.e.*, of single enantiomers of omeprazole or of any isolated or characterized salt of any optically pure omeprazole analogue.

(D.I. 86-2, col.1, ll. 43-47). This statement makes clear the patentees' view that that the prior art did not disclose any *salt* of optically pure omeprazole either as a single enantiomer or as an analog thereof. (Supp. Atwood Decl. ¶¶ 62-63.) Because the asserted salt claims of the '504 patent do not encompass the neutral form of omeprazole's enantiomers, there is no connection

with or reason to limit the optical purity of the claimed salts based on a prior art disclosure of neutral forms of the single enantiomers. (*Id.*) A person skilled in the art would simply not understand that the optical purity of the claimed salts is in any way limited or defined by the optical purity of the prior art enantiomers in neutral form. (*Id.*)

Even if Erlandsson's disclosure of (-)-omeprazole **neutral form** having an optical purity of 91.2% e.e., or the (+)-enantiomer's optical purity of 64% e.e.,[3] were relevant to the interpretation of the '504 patent claims, Dr. Davies provides no reason why the lower limit of optical purity of the **claimed salts** of (-)-omeprazole is 94% e.e., or why salts of (-)-omeprazole having an optical purity of, *e.g.*, between 91.2% e.e. and 94% e.e. would be outside the scope of the claims lacking any numerical optical purity limitation at all. In fact, the only disclosure of 94% e.e. is in Example 12, which is the neutral form of (-)-omeprazole and not its salt. The '504 patent does not have any disclosure whatsoever linking the optical purity of any salt form to 94% e.e. (*See* Supp. Atwood Decl. ¶ 64.)

Dr. Davies' methodology of (1) selecting as a starting point the prior art disclosure of the neutral form (-)-omeprazole as a basis for establishing a lower limit on the optical purity of the claimed salts, (2) arbitrarily importing the 94% optical purity value of the neutral form from Example 12 into the salt claims, and (3) failing to explain how or why compounds having an optical purity between 91.2% e.e. and 94% e.e. would not be included within his scope of the claims is flawed and unsupported. (Supp. Atwood Decl. ¶ 65.) In addition, Dr. Davies ignores the Erlandsson reference's teaching of (+)-omeprazole, obtained at an enantiomeric purity of 82% (64% e.e.) (D.I. 133-5, Ex. 8 at 317), and fails to explain why (even using his own flawed methodology) he did not consider the optical purity of the (+)-enantiomer in determining the

[3] As discussed below, whereas Dr. Davies cited to examples of the (+)-enantiomer to support his numerical limitations, he conveniently ignored the prior art value of 64% e.e. when creating his ranges.

lower limit of the '504 patent claims. (*Id.* ¶ 66.) AstraZeneca and Dr. Davies inconsistently and repeatedly rely on Examples 1, 3, 4 and 7 of the '504 patent (all directed to salts of (+)-omeprazole) to support his views about the interpretation of the claims (Davies App. pp. 3-4), but have wholly disregarded the prior art teachings of (+)-omeprazole in the Erlandsson reference in arbitrarily concluding the lower limit of the optical purity of the salts of claim 1 is 94% e.e. (Supp. Atwood Decl. ¶ 66).

The optical purities of the neutral forms of (-)-omeprazole in Example 12 and in the Erlandsson reference neither support nor limit the optical purities of the alkaline salts of (-)-omeprazole in the claims. (Supp. Atwood Decl. ¶ 67; D.I. 132-2, Atwood Decl. ¶¶ 34-35; Ex. 2, Atwood Tr. 190; 194-97; 222-24.) The enantiomers of omeprazole in non-salt or neutral form are not part of the invention of the '512 application as filed, because they were admittedly known in the prior art. There is no basis to limit the optical purity of a claimed (-)-omeprazole salt based on the prior art disclosure of the optical purity of a single enantiomer in neutral form. (*Id.*)

AstraZeneca's rationale for urging that "optically pure" of Claim 2 means at least 98% e.e. likewise embodies the improper tactic of limiting "optically pure" in the claims based on measured values for compounds reported in the Examples. (*See* Supp. Atwood Decl. ¶ 68.) Even using this improper methodology, none of the Examples support a 98% e.e. limitation. The closest value provided by the Examples for a (-)-omeprazole salt is 98.4% in Example 6, and Prof. Davies has not explained how the claims could encompass compounds having an optical purity between 98.0 - 98.4% e.e. Clearly, creating ranges by simply estimating or "rounding off" numerical values is not a canon of claim construction. The only example of a salt form at 98% e.e. is for a (+)-enantiomer (Example 3). (Supp. Atwood Decl. ¶ 68.)

The inconsistent and selective reliance on the teachings of the Erlandsson reference and the '504 patent Examples further highlights the fact that the there is simply nothing in the '504

patent documents which support adding any numerical limitations into the '504 claims, let alone the 94% - 98% e.e. values for salts. (Supp. Atwood Decl. ¶ 69.)

In summary, it is undisputed that:

- The '504 patent discloses no salt, much less a (-)-omeprazole salt, having an optical purity of 94% e.e.; therefore there is no basis for limiting Claim 1 to 94% e.e.

- With respect to Claim 2 of the '504 patent, there is no example of a (-)-omeprazole salt having an optical purity of 98% e.e.; therefore, there is no basis for limiting Claim 2 to 98% e.e.

- With respect to the claims of the '192 patent, discussed below, there is no example of a neutral (-)-enantiomer or a (-)-omeprazole salt having an optical purity of 98% e.e.; therefore there is no basis for limiting the '192 claims to 98% e.e.

- Because AstraZeneca's and Dr. Davies' methodology relies on reported values for non-claimed compounds in both the '504 and '192 patents, their baseline for the lower limit of the optical purity (which relies only on the (-)- enantiomer (91.2% e.e.) and not the (+)-enantiomer (64% e.e.)) is incorrect and therefore invalid.

(Supp. Atwood Decl. ¶¶ 70-71).

C. "administration of…", "administration to…" and "a mammal including man in need of treatment"

"administration of…" and "administration to…"

AstraZeneca's construction based on the route of administering ("delivery by any suitable means") makes no sense in the context of a method of treatment claim, involving a prescription drug, and which requires a determination of a therapeutically effective amount. How could a patient be "administered" a prescription drug such as Nexium® without a doctor? Who makes the decision about what would be an effective amount for a given patient suffering from a particular condition? The undisputed evidence is that Nexium® indeed does require a prescription,[4] and so will Hanmi's proposed product. Thus, contrary to AstraZeneca's statement

[4] AstraZeneca's argument that other unclaimed drugs, *e.g.*, Prilosec, do not need a prescription is irrelevant. The only commercial products of the '504 patent are prescription drugs.

that Hanmi's proposed construction is not "firmly anchored in reality" (*id.*), in fact Hanmi's proposed construction comports precisely with real world practice of the '504 patent's method claims. In fact, it is *AstraZeneca's* proposed construction, which encompasses non-oral delivery methods when the claims say "oral," which is "convoluted" and not "firmly anchored in reality." And, AstraZeneca properly concedes that, "a licensed healthcare professional or physician is required to diagnose and prescribe a prescription medicine," (AZ Br. 13) even though the specification does not per se mention that fact.

The excerpts cited by AstraZeneca's in support of its "delivery by any suitable means . . ." construction are directed to preparation of various forms pharmaceutical formulations ***to be administered***. *See* AZ Br. 13, citing col. 5, l. 25 - col. 6, l. 24 and col. 12, ll. 43-54 (describing preparation of pharmaceutical formulations in various forms (*e.g.*, tablets, capsules suppositories, solutions to be administered orally, rectally and parenterally) and do not speak to the meaning of the ***acts*** of "administration of . . ." or "administration to . . ." that are subject of the '504 claims.

AstraZeneca argues that the term "patient" does not trigger the requirement of the participation of a physician. Of course it does. Individuals who take non-prescription medications do not consider themselves patients. Tellingly, AstraZeneca has not responded to the evidence of record that 1) claimed methods and formulations are intended for clinical therapeutic use, 2) the ***act*** of administering/administration occurs in the context of methods where the need for inhibiting gastric acid secretion, or treatment of a disease/condition has been recognized and 3) therapeutically effective amounts will vary by patient/subject (Declaration of Dr. Robert Hardi, D.I. 132-1, ¶¶ 20-38.)

"a mammal including man in need of treatment"

As Hanmi previously noted, AstraZeneca's proposed construction for the language in claim 7 of "mammal including man in need of such treatment": "a mammal including man who

may obtain a benefit" (AZ Br. 15), reads the terms "in need" and "treatment" out of the claim. Hanmi's construction ("A mammal including man in whom the need for treatment of gatsrointestinal inflammatory disease is recognized and/or appreciated by the physician or other licensed healhcare professional") (D.I. 92-1, p. 20), is in line with its construction of "adminstration to" in claim 7 and the real world practice of the claims. *See Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1332-33 (Fed. Cir. 2003) ("a human in need thereof" requires that the "need" for therapy be recognized and appreciated and that the compound must be intentionally administered for treatment of the recited condition.) The combination of the phrase "treating or preventing" and the phrase "to a human in need thereof" compels a construction requiring the method to be practiced with the intentional purpose of achieving treatment of the condition recited in the claim. *Id.* at 1333, *citing Rapoport v. Dement*, 254 F.3d 1053, 1061 (Fed. Cir. 2001).

II. Hanmi's Proposed Constructions For The '192 Patent Should Be Adopted

A. "pharmaceutically acceptable salt"

AstraZeneca simply reasserts its definition of "alkaline salt" from the '504 patent, largely ignoring the express definition of "pharmaceutically acceptable salt" appearing at col. 4, lines 13-16 of the '192 patent (D.I. 111-9). AstraZeneca's proposed construction should not be adopted for several reasons.

First, the express definition at column 4, lines 13-16 -- "both acid and alkaline pharmaceutically acceptable non-toxic salts" – cannot just be brushed aside. (*See* Hanmi Opening Br. 20-22; Supp. Atwood Decl. ¶ 43.)

Second, AstraZeneca argues that the specification's definition of "pharmaceutically acceptable salt" does not relate to salts of (-)-omperazole, but instead relates to salts of the optional other therapeutic ingredients mentioned in the paragraph at issue. (AZ Br. 18.) This argument is a total stretch, and is undermined by the very language of the patent:

> The pharmaceutical compositions of the present invention comprise ***the (-)-enantiomer of omeprazole as active ingredient, or a pharmaceutically acceptable salt thereof***, and may also contain a pharmaceutically acceptable carrier and optionally other therapeutic ingredients. The term ***"pharmaceutically acceptable salt"*** refers to both acid and alkaline pharmaceutically acceptable non-toxic salts. Compositions comprising other therapeutic ingredients are especially of interest in the treatment of Helicobacter infections.

D.I. 111-9, col. 4, ll. 9-18 (emphasis added); Supp. Atwood Decl. ¶¶ 45-46. It is plain that the quoted phrase "pharmaceutically acceptable salt" expressly defines the exact term used in the preceding sentence, which clearly is the (-) enantiomer of omeprazole and not the other therapeutic ingredients. AstraZeneca's contrary argument is untenable: persons of ordinary skill in the art would not read the acid or alkaline salts of the "pharmaceutically acceptable salt" definition to describe anything other than (-)-omeprazole salts. (Supp. Atwood Decl. ¶¶ 43-47.)

Third, AstraZeneca raises the issue of esomeprazole's stability in acidic conditions, apparently suggesting that acid salts of (-)-omeprazole could not be formed, and would not be stable. This position should likewise be rejected. Dr. Davies concedes that acid salts indeed can be formed: "(-)-omeprazole is 'amphoteric,' which means that it is able to form a salt either under basic conditions by loss of a proton or under acidic conditions by addition of a proton." (Davies Declaration, D.I. 133-3, ¶ 38.) Dr. Davies further illustrates formation of both acid and alkaline salts, and he depicts each as well. (*Id.* ¶¶ 39-40.) The literature is replete with examples of acid salts of omeprazole. (Supp. Atwood Decl. ¶¶ 48-56.) Thus, any suggestion that acid salts could not be made or wouldn't work is incorrect and unsupported. (*See also* Supp. Atwood Decl. ¶ 51.)

B. "consisting essentially of"

AstraZeneca relies completely on the prior construction, where the Court found that "consisting essentially of," added to the claims during prosecution, "means a (-)-enantiomer that is essentially free of its (+)-contaminant, which means at least 98% e.e. " *AstraZeneca AB v. Dr.*

Reddy's Labs., Ltd., et al., ("AZ v. DRL") 2010 U.S. Dist. LEXIS 48844 at*29-30 (D.N.J. May 17, 2010).

When a phrase is added to a patent claim during prosecution, the phrase must find either explicit or inherent support in the original patent application as filed. However, the Patent Office and the Courts have developed special rules governing the meaning of and permitting the use of legal transition phrases, such as "consisting essentially of," even where the term is not disclosed in the original application. (Hanmi Br. 23-24). Here, because the phrase "consisting essentially of" does not appear in the original '962 application as filed but instead was added to all of the claims during prosecution, it can only be according its standard legal meaning. Otherwise, its addition to later-added claims would be impermissible new matter. *Agilent Techs., Inc. v. Affymetrix, Inc*., 567 F.3d 1366, 1379 (Fed. Cir. 2009) ("The written description doctrine prohibits new matter from entering into claim amendments . . . .").

C. "(-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" -- Optical Purity

AstraZeneca's position is based on the parent '512 application being incorporated by reference into the '192 patent -- an issue in dispute. (*See* Hanmi Br. 25-27). Hanmi has urged that the attempted incorporation fails the "detailed particularity" standard, and noted that whether material has been incorporated by reference, and the extent of its incorporation, is a question of law, considered under a reasonable person of ordinary skill in the art standard. *Zenon Envtl., Inc. v. U.S. Filter Corp*., 506 F.3d 1370, 1378-79 (Fed. Cir. 2007). Astrazeneca has failed to meet this standard. At his deposition, Dr. Davies could not succinctly identify what portions of the parent '512 application one of ordinary skill in the art would have considered to be incorporated. (*See* Ex. 1, Davies Tr. at 187-202). Because AstraZeneca's attempted incorporation fails the particularity standard, the '512 application provides no support for its optical purity construction.

Moreover, even if, *arguendo*, some portion or the entirety of the '512 application is determined to have been incorporated into the '192 specification, the claims still are not limited to 98% e.e. for the reasons discussed in Section I.B. above with respect to the '504 patent claims.

Additionally, particularly with respect to the '192 patent claims which encompass both the neutral form of the (-)-enantiomer and pharmaceutically acceptable salts thereof, there is no disclosure in the '504 patent of a neutral form of a ***(-)***-enantiomer having an optical purity of 98%. The only example of a free enantiomer reported as 98% e.e. is Example 13 directed to a ***(+)***-enantiomer. And there is no disclosure in the '504 patent of a (-)-omeprazole salt having an optical purity of 98% e.e. Thus, even if the claims could be limited to numerical values found only in illustrative working examples (which they cannot), the Examples do not support the conclusions drawn. (Supp. Atwood Decl. ¶¶ 70-71).

D. "administering to a mammal in need of treatment"

As with the '504 patent (see section I.C. above), AstraZeneca's construction based on the route of administering ("delivery by any suitable means") is incorrect in the context of a method of treatment claim, involving a prescription drug, and which requires a determination of a therapeutically effective amount. The only issue is whether the presence of a physician is required (Hanmi) or merely optional (AstraZeneca) and the evidence is undisputed that Nexium does require a prescription (Hanmi Br. 17, 29), so AstraZeneca's position is inconsistent with the record and the real world practice of the claims.

The context of the claims, directed to methods of treatment, make clear that only a physician can determine the "therapeutically effective amount" of the drug product which is only available by prescription. Hardi Decl. ¶¶ 30-33 and 35-38 (D.I. 132-1).

Because claims 1 and 2 of the '192 patent require that the mammal is "in need of treatment," one of ordinary skill in the art would recognize that the diagnosis of a physician is required. *Id.* ¶ 34. Who other than a physician can determine whether a patient is in need of

treatment with esomeprazole – a prescription drug? AstraZeneca's proposed construction for 'mammal in need of treatment' as merely one 'who may obtain a benefit' (D.I. 133, p. 20) fails to give significance to the claim language "in need of" and "treatment" and should not be adopted.

III. AstraZeneca's Has Fully Briefed Its Alleged "Claim Construction" Issues In The Summary Judgment Record

In Section V at page 22 (D.I. 133), AstraZeneca again raises alleged "claim construction" issues from Hanmi's summary judgment motions. However, the Court's November 1, 2011 instructions made clear that AstraZeneca was to present its alleged "claim construction" issues in its summary judgment opposition briefs, and not in the present *Markman* briefing. As to AstraZeneca's request that Hanmi's Motions 1 and 3 be considered at the same time as *Markman* issues, Hanmi would be pleased to address the fully-briefed summary judgment motions at any time should the Court desire.

As demonstrated below, Hanmi's Motions 1 and 3 do not raise issues of claim construction. However, if AstraZeneca is suggesting some sort of piecemeal extraction of what it characterizes as "claim construction" issues apart from the merits of each motion, Hanmi respectfully submits that its Motions 1 and 3 should be taken up as a whole.

A. Hanmi's Motion No. 3 – "Solid State" in the '504 Patent Claims

AstraZeneca is incorrect that Hanmi's Motion No. 3 raised an issue of "claim construction" with respect to the term "solid state" in the '504 patent claims. Hanmi's Motion No. 3 raised *invalidity* issues – lack of written description, lack of enablement and indefiniteness. D.I. 115 at 5-11, 12-20 and 21-23, respectively. Indeed, based on the intrinsic and extrinsic record, *Hanmi has no claim construction to proffer.* AstraZeneca gives an incomplete statement of the prior *AZ v. DRL* proceeding.

In reliance on the Court's prior rejection of "solid state" as meaning "solid form rather

than liquid, such as syrup or oil" (D.I. 106, ¶¶ 65-66), and in view of the lack of any disclosure or discussion of the term in the '512 application as filed, Hanmi asserted lack of written description, non-enablement and indefiniteness defenses in its May 25, 2011 invalidity contentions (D.I. 87-1, pp. 73-76 and 80-81). Both then and now, ***Hanmi has no claim construction to proffer***, because the intrinsic record provides no single clear meaning and the art uses the term in various ways, as established on the present summary judgment record.

AstraZeneca cannot interject new "claim construction" issues into the *Markman* track at this stage because in the November 1, 2011 teleconference, the Court clearly instructed AstraZeneca to present its position in its summary judgment opposition. Moreover, with Hanmi's "solid state" invalidity contentions in hand since May, 2011, AstraZeneca let every *Markman* deadline in the case pass without mentioning "solid state." Hanmi's Motion 3 and AstraZeneca's opposition present the parties' respective positions, and Hanmi's is not one of claim construction.

B. Hanmi's Motion No. 1 Does Not Raise Claim Construction Issues

Hanmi's Motion No. 1 presents a straightforward application of the '192 patent's "comparative" claim terms as construed by the Court in related action *AstraZeneca v. Dr. Reddy's Laboratories, Ltd., et al*, 05-5553 (JAP) ("DRL Action") (D.I. 105, SOF ¶¶ 49-52), that were mutually adopted by the parties in this action (D.I. 105, SOF ¶ 49; D.I. 92). AstraZeneca urges that Hanmi's motion "turns on an issue of claim construction" (D.I. 146, Opposition Brief ("Opp.") at 3), but AstraZeneca never raised any issue of "claim construction" when served with Hanmi's non-infringement contentions in May, 2011, and the only alternative construction AstraZeneca seems to now argue is the very one it successfully opposed in the DRL Action.

Motion 1 does not present an issue of "claim construction" as now urged by AstraZenenca. To the contrary, Hanmi relied upon the precise language of the agreed prior constructions and established non-infringement. Again, AstraZeneca had Hanmi's current,

detailed non-infringement contentions in hand on May 25, 2011 (D.I. 105, ¶ 91, citing D.I. 87-1), yet chose not to raise any claim construction issues as to the terms at issue in the subsequent *Markman* phase of the present case. The Joint Claim Construction Statement (D.I. 92) adopted the parties' agreed constructions of these terms. Motion No. 1 provides the proper context to apply the agreed constructions to Hanmi's conduct, and there is no need for any separate "claim construction" apart from the fully briefed motion.

IV. Claims 3 and 10 Of The '504 Patent Do Not Require Construction Because They Are Facially Invalid

Claims 3 and 10 were added to the case on November 14, 2011 (D.I. 139) over Hanmi's objection. On December 9, 2011, Hanmi asserted that claims 3 and 10 were invalid for failure to satisfy the written description and indefiniteness requirements of 35 U.S.C. § 112, first and second paragraphs because the "R" group is an undefined variable in a chemical formula. (Ex. 15, Hanmi's Amended Contentions at 75-78 and 89). In correspondence three days ago, AstraZeneca asserted it would raise the scope of the "R" group in claims 3 and 10 in its responsive *Markman* brief (Ex. 14). Hanmi disagrees that "R" requires construction because R stands as undefined variable in a chemical formula and claims 3 and 10 are facially invalid. Because AstraZeneca plans to brief the issue of R in its responsive *Markman* brief, Hanmi sets forth its position as well, which is based on invalidity and not claim construction.

The '504 patent was filed as U.S. Application Serial No. 08/376,512 ("the '512 application") on January 23, 1995. (D.I. 86-2 cover page; D.I. 111 (certified copy of '504 patent file history), '512 Application at HAN0039510.) There were 34 claims in the '512 application as originally filed. (*Id.*, '512 application at HAN0039543-49.) Consistent with the scope of the original specification filed on January 23, 1995, most of the original claims of the '512

application were directed to the six particular salt compounds of omeprazole's enantiomers.[8] Original claim 1 of the '512 application is representative:

> 1. An optically pure enantiomeric compound comprising a Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole, ***wherein R is an alkyl with 1-4 carbon atoms***.

(D.I. 111 at HAN0039543 (emphasis added).) None of claims 1-34 of the '512 application as originally filed generically claimed an "alkaline salt" of (-)-omeprazole; instead, all original claims to the enantiomers were directed to only these six salt species, or a subset of them (*e.g.*, claim 30), and in all relevant claims R was defined as an alkyl group with 1-4 carbon atoms ("C1-4 alkyl"). (D.I. 111 at HAN0039543-49.)

On August 12, 1996, claim 1 and other original enantiomer claims were rejected for various reasons. (D.I. 111, August 12, 1996 Office Action at HAN0039578-80.) In a February 12, 1997 Amendment, AstraZeneca cancelled all of original claims 1-34 and added new claims 35-44, which later issued as claims 1-10 of the '504 patent. These new claims introduced the term "alkaline salt" in the independent claims for the first time, in contrast to the original claims discussed above which were limited to the six salts, and dependent claims 37 and 44 (which became '504 patent claims 3 and 10) defined the alkaline salt as "a Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt." (D.I. 111-2, February 12, 1997 Amendment at HAN0039757-70.) In the new claims, R was not defined at all, in contrast to the original specification and claims. AstraZeneca did not point to any support in the specification for claiming a genus of $N^+(R)_4$ salts where R was other than C1-4 alkyl.

Further, it is undisputed that the original specification identifies R as C1-4 alkyl. (D.I. 86-2, Abstract and col. 2, ll. 42-49). Nonetheless, in the precise context of claims 3 and 10, the

[8] Claims to a heterocyclic intermediate and processes of preparing particular compounds were also present, but are not relevant to salt scope.

traditional definition-oriented approach to claim construction does not apply to R because the claim defines a class of chemical compounds by the structural formula "$N^{+}(R)_4$" -- and R merely stands as an undefined variable. Claims to chemical compounds require precision, and AstraZeneca cannot avoid the consequences of its own actions taken during prosecution. *See e.g., Ex parte Diamond,* 123 USPQ 167 (Pat. Off. Bd. App. 1959) (Ex. 16) (Claim 1 held unpatentable because the chemical formula contained undefined substituents).

Here, R is meaningless in claims 3 and 10. The scope of these claims is literally unbounded. Claims to chemical compounds often include structural formula with variables, such as R here, but the common and accepted practice is to define all variables in the claim itself; indeed AstraZeneca cites no support for its position that an applicant can drop a claim definition of a variable in a chemical formula during prosecution, then come back in litigation and ask the Court to read the dropped definition back into the claim. Further, AstraZeneca has not cited a single patent containing undefined variables in claims including chemical formulas. The Federal Circuit has considered chemical genus claims on a number of occasions, including the recent *en banc* decision in *Ariad Pharms., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 (Fed. Cir. 2010), where the court discussed such claims as having "boundaries" akin to a "fence". 598 F.3d at 1349-50. Here, claims 3 and 10 lack the fence.

Based on the prosecution record, the scope of claims 3 and 10 can be viewed as (a) an intentional broadening by AstraZeneca, in which case that broadened concept results in the claims being invalid under 35 U.S.C. § 112, first paragraph, for violating the written description requirement because the original '512 application fails to describe a class of $N^{+}(R)_4$ salts where R is unbounded and not limited to C1-4 alkyl groups; or (b) an oversight or mistake, in which case AstraZeneca has had since 1998 to correct via reissue under 35 U.S.C. § 251 but has not. In either case, AstraZeneca should not be permitted to drop a claim definition during prosecution and then seek to have it to have it returned in a "claim construction" context to preserve validity.

And, if the definition of R was omitted by mistake, it is not the function or province of courts to repair claims, such as claims 3 and 10, under the guise of claim construction. It is well-settled that courts may not redraft claims, whether to make them operable or to sustain their validity. *Chef Am., Inc. v. Lamb Weston, Inc.,* 358 F.3d 1371, 1373-74 (Fed. Cir. 2004)[10]; *see also BMC Res., Inc. v. Paymentech, L.P.,* 498 F.3d 1373, 1378 (Fed. Cir. 2007) ("Courts will not unilaterally restructure claims or standards for infringement to remedy a patentee's ill-conceived claims. "); *Helmsderfer v. Bobrick,* 527 F.3d 1379, 1383-1384 (2008) ("Courts cannot rewrite claim language. 'Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.'; '[C]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth.'") (citations omitted). As between the patentee who had a clear opportunity to negotiate broader (or narrower) claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to properly seek protection of its invention in a manner consistent with elementary constructs of the patent law. *See Sage Prods. Inc. v. Devon Indus. Inc.,* 126 F. 3d 1420, 1425 (Fed. Cir. 1997); *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1349 (Fed. Cir. 2002). To redraft the clear language of the claims to mean something else "would unduly interfere with the function of claims in putting competitors on notice of the scope of the claimed invention." *Hoganas AB v. Dresser Indus.*, 9 F.3d 948, 951 (Fed. Cir. 1993).

As shown above, in claims 3 and 10, one of the recited salt forms is an $N^{+}(R)_4$ salt. However, unlike the specification which refers to R as a C1-4 alkyl group (D.I. 86-2, Abstract and col. 2, ll. 42-49), claims 3 and 10 are not so restricted. R simply exists in the chemical

[10] Citing *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1349 (Fed. Cir. 2002); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.,* 214 F.3d 1302, 1308-09 (Fed. Cir. 2000); *Process Control Corp. v. Hydreclaim Corp.,* 190 F.3d 1350, 1357 (Fed. Cir. 1999); *Rhine v. Casio, Inc.,* 183 F.3d 1342, 1345 (Fed. Cir. 1999); *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 799 n.6 (Fed. Cir. 1990).

formula as an undefined variable. Given that AstraZeneca chose to claim the $N^+(R)_4$ salt type more broadly in claims 3 and 10 than is disclosed or claimed in the original '512 application, which provides no further disclosure of suitable R groups other than C1-4 alkyl groups, the subject matter of claims 3 and 10 clearly violates the written description requirement, and therefore claims 3 and 10 are invalid under 35 U.S.C. § 112, first paragraph.

Claims 3 and 10 are also invalid under 35 U.S.C. § 112, second paragraph, because the recited $N^+(R)_4$ salt is literally unbounded. As discussed above, chemical genus claims must be bounded by a fence. Given AstraZeneca's choice to claim the $N^+(R)_4$ salt type more broadly than it is disclosed in the specification, which discloses only that suitable R groups are C1-4 alkyl, one of ordinary skill in the art would be unable to determine with reasonable particularity the boundaries of claims 3 and 10 with respect to the scope of the $N^+(R)_4$ salt type, and therefore claims 3 and 10 are fatally indefinite and invalid under 35 U.S.C. § 112, second paragraph.

Dated: January 6, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on January 6, 2012, I caused a copy of the foregoing HANMI'S RESPONSIVE *MARKMAN* SUBMISSION to be served upon the following counsel through the Court's ECF system and viae- mail:

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